

# Executive Summary

This paper discusses and analyses the pharmaceutical intellectual property (IP) environment in Canada. In particular it examines the evolutionary process underlining the policymaking of intellectual property rights (IPRs) in the field of pharmaceuticals, with a focus on Canadian policy since the 1970s. The paper also seeks to compare these policy developments with some key legal rulings handed down by the Canadian judiciary. It identifies a potential contradiction between the legal and regulatory framework introduced in Canada since 1992 – a framework which is more supportive of the domestic innovative pharmaceutical sectors – and some of these key court rulings. The latter tend to provide a legal interpretation of pharmaceutical IPRs that seems to be based on a rationale reminiscent of the pro-generic IPR policy of the 1970s and 1980s, rather than the one established in the early 1990s.

This potential contradiction should be addressed since it affects the *de facto* nature and direction of the contemporary pharmaceutical environment in Canada. A greater emphasis should be placed on the fact that over the last two decades, Canada has experienced (and is experiencing) a noticeable and ongoing shift of policy towards more robust systems of IP protection, aimed at supporting the innovative segment of the domestic pharmaceutical and biotechnology sectors. This change of policy, however, should not only be limited to the policymaking level but should also "spill over" to the judiciary. This is not to argue that policies aimed at supporting the production and dissemination of generic drugs should not take place in Canada. Such policies are relevant and important to any country's health care system. Yet these policies are only part of the equation and not a wholesale solution. Indeed, experience suggests that it is possible to combine both a pro-innovation policy with a pro-generic one without sacrificing either. For example, the United States, while having its own problems with the high cost of drugs, actually has the highest rate of market penetration of generics in the world yet, at the same time, has a very robust system of IP protection. Popular misconceptions about the cost-cutting benefits of favouring a large generic sector should be engaged and where appropriate refuted.

Structurally, the paper does the following:

- i) provides a brief overview of the pharmaceutical industry, and the process of drug discovery and development, as well as of the IPRs that are relevant to this field;
- ii) analyses the Canadian health care model in the context of the fundamental shift from a generics-based mentality towards one that is more pro-innovator;
- iii) analyses several key rulings, which seem to suggest that the Canadian courts are not consistent in their interpretation of this broad shift in IPR policy; and
- iv) finally, the paper provides policy recommendation that seek to address the seeming gap between the legislative and the judicial.